K113289
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AUG 1 2012

1. 510(k) Summary

The information in this 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92(c).

510(k) Owner: Micro Therapeutics d/b/a ev3 Neurovascular
9775 Toledo Way
Irvine, CA 92618
Establishment Registration No. 2029214

Contact Person: Analia Nieto
Regulatory Affairs Specialist
Telephone: (949) 680-1201
E-mail: anieto@ev3.net

Date Summary Prepared: July 31, 2012

Trade Name of Device: Orion™ Micro Catheter

Common Name of Device: Catheter, Continuous Flush

Classification of Device: KRA, Class II

Predicate Device: Micro Therapeutics, Inc. d/b/a ev3 Neurovascular, Rebar® Micro Catheter, K993672

Cordis Neurovascular, Inc., PROWLER® SELECT® Plus Infusion Catheter, K021591

Device Description: The Orion™ Micro Catheter is a .021 inch size delivery catheter. The construction consists of a proximal stainless steel hypotube for pushability, and a distal multi-durometer Pebax shaft with progressive pitch Nitinol braid reinforcement. A continuous PTFE liner provides an uninterrupted, smooth inner diameter for low friction stent delivery. The proximal hub is molded from a DMSO compatible polymer. The distal shaft incorporates 2 radiopaque marker bands to aid with stent or coil detachment.

Intended Use: The Orion™ Micro Catheter device is intended for the controlled selective infusion of physician-specified therapeutics agents or contrast media into the vasculature of the peripheral and neuro anatomy.

Non-Clinical Performance Data:

Biocompatibility Testing

- Cytotoxicity
- Sensitization
- Intracutaneous
- Systemic Toxicity
- Pyrogen
- Coagulation UPPT
- Thromboresistance
- Complement Activation C3a and SC5b-9 Assy

Bench Testing

- Aspiration Testing
- Catheter Particle Testing
- Catheter Tip Shape Retention
- Catheter Trackability Coating Performance
- Catheter Coating Integrity
- Dimensional Inspection
- Distribution Simulation
- DMSO Compatibility Testing
- Dynamic Pressure Burst Test
- Enterprise Stent Compatibility Testing
- Flow Rate Test
- Kink Diameter and Lumen Concentricity
- Static Pressure Test
- Tensile Strength Test
- Tortuous Neurovascular Model

In-Vitro Design Validation Study

- Pushability
- Navigability
- Radiopacity
- Stent Delivery Friction
- Stability
- Ability to Cross Clot

Shelf-life Testing

- 6-month Accelerated Aging

Substantial Equivalence Determination

The information presented in the 510k shows that the Orion™ Micro Catheter is substantially equivalent to the Rebar® Micro Catheter and PROWLER® SELECT® Plus in regards to the similar indications for use, device design, device materials, device dimensions, and materials comprising its accessories and final packaging, and design specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 1 2012

Micro Therapeutics, Inc.
c/o Ms. Analia Nieto
Regulatory Affairs Associate
9775 Toledo Way
Irvine, CA 92618

Re: K113289
Trade/Device Name: Orion Micro Catheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Catheter, Continuous Flush
Regulatory Class: Class II
Product Code: KRA
Dated: July 23, 2012
Received: July 24, 2012

Dear Ms. Nieto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113289

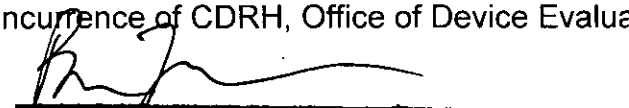
Device Name: Orion™ Micro Catheter

Indications for Use: The Orion™ Micro Catheter device is intended for the controlled selective infusion of physician-specified therapeutics agents or contrast media into the vasculature of the peripheral and neuro anatomy.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K113289